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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,473	04/08/2004	Wei Chen	900.1009US	1056

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EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
06/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,473	CHEN ET AL.	
	Examiner	Art Unit	
	ALI SOROUSH	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-57,59,60 and 62-113* is/are pending in the application.

4a) Of the above claim(s) *106-113* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-57,59,60 and 62-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/22/2008 has been entered.

Status of the Claims

Claims 1-53, 58, and 61 are cancelled and claims 54, 57, and 106-113 are currently amended. Therefore claims 54-57, 59, 60, and 62-113 are currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claims 106-113 have been amended to recite "A method of purifiying the trans-capsaicin product". This amendment would place the instant claims in to Group II as described in the restriction requirement in the Office Action mailed on 10/17/2006. Applicant in response to the restriction requirement elected without traverse to

prosecute claims of Group III (product trans-capsaicin) in the response filed on 12/21/2006. Therefore, claims 106-113 are withdrawn from consideration as being drawn to non-elected subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 54-57, 59, 60 and 63-105 are rejected under 35 U.S.C. 102(b) as being anticipated by Limlomwongse et al. (Journal of Nutrition, pp. 773-777, Published 05/1979) as evidenced by Jancso et al. (British Journal of Pharmaceutical Chemotherapy, pp. 138-151, Published 1967).

Limlomwongse et al. teaches delivery of varying doses of pure synthetic capsaicin, in saline solution, into the lumen of rat via a gastric fistula. (See abstract). Jancso et al. defines capsaicin as trans-N[4'-hydroxy-3'-methoxy-benzyl]-8-methylnon-6-enamide. With regard to the amount of purity claimed in claims 58-60 these would necessarily be taught by Limlomongse et al. because Limlomongse et al. teaches the capsaicin is synthetically derived and pure therefore it would be approximately 100% trans-capsaicin. It is noted that the recitation of the intended use "treatment of nociceptive pain, neuroceptive pain, pain from nerve injury, pain from neuralgia ..."

(claim 55) and "treatment of orthopedic disorders selected from ..." (claim 56) has not been given patentable weight to distinguish over **Limlomwongse et al.** because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since **Limlomongse et al.** discloses compounds that are the same as those claimed, they would be capable of performing the intended use, as claimed. Therefore, the reference is deemed to anticipate the instant claims above. In a claim to a composition a statement to the composition's intended use has no patentable weight since the intended use does not structurally change or add component(s) to the composition. With regard to limitations in claims 54 and 63-113 related to the process by which capsaicin is prepared, product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. "The patentability of the product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Circ. 1985)" (See MPEP 2113).

Applicant has argued that the synthetic trans-capsaicin taught by Limlomwongse et al. are provided from Sigma-Aldrich and are from natural sources and therefore does not contain >97% capsaicin but more likely contains a composition comprising

capsacinoids with only 69% capsaicin present. Applicant's arguments have been fully considered and found not to be persuasive. Limlomwongse et al. specifically teach that their capsaicin is a "synthetic" capsaicin acquired from Sigma Chem Co. (See page 774, column 2, Footnote 1). As applicant has indicated Sigma provides 5 capsaicin products. Two of these products natural and BioChemika, from Capsicum sp. indicate a 65% capsaicin and 35% dihydrocapsaicin. The other 3 products ≥95% from Capsicum sp., puriss. ≥99%, BioChemika ≥97% only list capsaicin being present. Therefore, it is believed that wherein Limlomwongse et al. indicates a "pure synthetic capsaicin" acquired from Sigma Chem. Co. this would indicate the highest purity possible which is the puriss. ≥99% product. Therefore, it is the examiners position that wherein Limlomwongse et al. teach a "pure synthetic capsaicin", what is indicated is a synthetically derived capsaicin of ≥99% purity and therefore reads on the instant claims. For the foregoing reasons the instant invention is anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Limlomwongse et al. (Journal of Nutrition, pp. 773-777, Published 05/1979) in view of Guenzler-Pukall et al. (US 2004/0204356 A1, Published 10/14/2004).

Applicant Claims

A pharmaceutical composition comprising trans-capsaicin comprising about 99% or greater trans-capsaicin and vehicle suitable for injection wherein the vehicle comprises about 20% PEG 300, about 10 mM histidine and about 5% sucrose in water.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Limlomwongse et al. is disclosed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Limlomwongse et al. does not expressly teach using a pharmaceutical vehicle comprising polyethylene glycol (PEG 300), histidine, and sucrose. Teachings of Guenzler-Pukall et al. cure this deficiency.

Guenzler-Pukall et al. teaches, "**Suitable carriers for intravenous injection** of the invention is well known in the art and include **water-based solutions containing a base**, such as, for example sodium hydroxide, to form an ionized compound, **sucrose** or sodium chloride **as tonicity agent**, for example, **the buffer** contains phosphate or **histidine**. **Co-solvents**, such as, for example, **polyethylene glycols, maybe added**. These water-based systems are effective at dissolving the compound of the invention and produce low toxicity upon systemic administration. The proportions of a solution system may be varied considerably, without destroying solubility and toxicity characteristics." (See page 13, paragraph 0137).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to incorporate various conventional pharmaceutical carriers (vehicles) such as PEG's, histidine, and sucrose within the injectable compositions taught by Limomwongse et al. based on the beneficial teachings provided by Guenzler-Pukall et al. which discloses that such conventional carrier (vehicles) are suitable therfor. The adjustment of particular conditions (e.g. determining appropriate amount ranges of carriers including PEG, histidine, and sucrose therein) is deemed merely a matter of judicious selection and routine optimization which is well within the

purview of the skilled artisan. For the foregoing reasons given the instantly claimed invention is made obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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